

AMENDED IN SENATE APRIL 21, 2010

AMENDED IN SENATE APRIL 7, 2010

**SENATE BILL**

**No. 971**

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**Introduced by Senator Pavley**

February 8, 2010

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An act to add Article 5 (commencing with Section 125286.1) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic disease services.

LEGISLATIVE COUNSEL'S DIGEST

SB 971, as amended, Pavley. Bleeding disorders: blood clotting products.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use, *as described*, used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions, *except as provided*.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1     SECTION 1. Article 5 (commencing with Section 125286.1)  
2     is added to Chapter 2 of Part 5 of Division 106 of the Health and  
3     Safety Code, to read:

4  
5     Article 5. Standards of Service for Providers of Blood Clotting  
6                     Products for Home Use Act  
7

8     125286.1. This article shall be known, and may be cited, as  
9     the Standards of Service for Providers of Blood Clotting Products  
10    for Home Use Act.

11    125286.2. The Legislature hereby finds and declares all of the  
12    following:

13    (a) Hemophilia is a rare, hereditary, bleeding disorder affecting  
14    at least 4,000 persons in California and is a chronic, lifelong, and  
15    incurable, but treatable, disease.

16    (b) Von Willebrand disease is a human bleeding disorder caused  
17    by a hereditary deficiency or abnormality of the von Willebrand  
18    Factor in human blood, which is a protein that helps clot blood.  
19    Von Willebrand disease is a chronic, lifelong, incurable, but  
20    treatable, disease affecting at least 360,000 Californians.

21    (c) Until the 1970s, people with severe hemophilia suffered  
22    from uncontrollable internal bleeding, crippling orthopedic  
23    deformities, and a shortened lifespan. More recently, the production  
24    of highly purified blood clotting factors have provided people with  
25    hemophilia and other bleeding disorders with the opportunity to  
26    lead normal lives, free of pain and crippling arthritis.

27    (d) The preferred method of treatment of hemophilia today is  
28    intravenous injection, or infusion, of prescription blood clotting  
29    products several times per week, along with case management and  
30    specialized medical care at a federally designated regional  
31    hemophilia treatment center.

32    (e) Pharmacies and other entities specializing in the delivery of  
33    blood clotting products and related equipment, supplies, and  
34    services for home use form a growing enterprise in California. All  
35    of these entities are licensed by the state or are located at federally  
36    designated regional hemophilia treatment centers, or both.

37    (f) Timely access to federally designated regional hemophilia  
38    centers and appropriate products and services in the home,

1 including infusion of blood clotting products and related  
2 equipment, and supplies and services for persons with hemophilia  
3 and other bleeding disorders, reduces mortality and bleeding-related  
4 hospitalizations, and is extremely cost effective, according to the  
5 federal Centers for Disease Control and Prevention and the Medical  
6 and Scientific Advisory Council of the National Hemophilia  
7 Foundation.

8 (g) Eligible persons with hemophilia or other bleeding disorders  
9 may receive treatment through the Genetically Handicapped  
10 Persons Program, the California Children's Services Program, and  
11 Medi-Cal. Access to quality blood clotting products for home use  
12 and related equipment, supplies, and services for people with  
13 hemophilia or other bleeding disorders promotes cost containment  
14 in each of these publicly funded programs as well as in the health  
15 insurance and health care industries more generally.

16 (h) For the benefit of persons with hemophilia or other bleeding  
17 disorders, as well as for cost containment in health care, the  
18 purposes of this article are to do the following:

19 (1) Establish standards of service for entities that deliver blood  
20 clotting products and related equipment, supplies, and services for  
21 home use.

22 (2) Promote access to a full range of essential, cost effective,  
23 lifesaving, blood clotting products and related equipment, supplies,  
24 and high-quality services for home use for persons with hemophilia  
25 and other bleeding disorders.

26 125286.3. (a) Unless *the* context otherwise requires, the  
27 following definitions shall apply for purposes of this article:

28 ~~(a)~~

29 (1) "Assay" means the amount of a particular constituent of a  
30 mixture or of the biological or pharmacological potency of a drug.

31 ~~(b)~~

32 (2) "Ancillary infusion equipment and supplies" means the  
33 equipment and supplies required to infuse a blood clotting product  
34 into a human vein, including, but not limited to, syringes, needles,  
35 sterile gauze, field pads, gloves, alcohol swabs, numbing creams,  
36 tourniquets, medical tape, sharps or equivalent biohazard waste  
37 containers, and cold compression packs.

38 ~~(c)~~

39 (3) "Bleeding disorder" means a medical condition characterized  
40 by a deficiency or absence of one or more essential blood clotting

1 proteins in the human blood, often called “factors,” including all  
2 forms of hemophilia and other bleeding disorders that result in  
3 uncontrollable bleeding or abnormal blood clotting without  
4 treatment.

5 ~~(d)~~

6 (4) “Blood clotting product” means an intravenously  
7 administered medicine manufactured from human plasma or  
8 recombinant biotechnology techniques, approved for distribution  
9 by the federal Food and Drug Administration, that is used for the  
10 treatment and prevention of symptoms associated with bleeding  
11 disorders. Blood clotting products include, but are not limited to,  
12 Factor VII, Factor VIIa, Factor VIII, and Factor IX products, von  
13 Willebrand Factor products, bypass products for patients with  
14 inhibitors, and activated prothrombin complex concentrates.

15 ~~(e)~~

16 (5) “Consumer” means a person needing a blood clotting product  
17 for home use.

18 ~~(f)~~

19 (6) “Emergency” means a situation in which a prudent layperson  
20 could reasonably believe that the consumer’s condition requires  
21 immediate medical attention.

22 ~~(g)~~

23 (7) “Hemophilia” means a human bleeding disorder caused by  
24 a hereditary deficiency of the Factors I, II, V, VIII, IX, XI, XII,  
25 or XIII blood clotting protein in human blood.

26 ~~(h)~~

27 (8) “Hemophilia treatment center” means a facility for the  
28 treatment of bleeding disorders, including, but not limited to,  
29 hemophilia, that receives funding from ~~the~~ federal government  
30 sources, including, but not limited to, the federal Centers for  
31 Disease Control and Prevention and the federal Health Resources  
32 and Services Administration (HRSA) of the United States  
33 Department of Health and Human Services.

34 ~~(i)~~

35 (9) “Home nursing services” means specialized nursing care  
36 provided in the home setting to assist a patient in the reconstitution  
37 and administration of blood clotting products.

38 ~~(j)~~

39 (10) “Home use” means infusion or other use of a blood clotting  
40 product in a place other than a state-recognized hemophilia

1 treatment center. Places where home use occurs include, without  
2 limitation, a home or ~~physician~~ *physician's* office.

3 ~~(k) "Provider of blood clotting products for home use" means~~  
4 ~~a seller and provider of blood clotting products, ancillary infusion~~  
5 ~~equipment, home nursing services, and patient assistance for the~~  
6 ~~management of bleeding disorders for home use.~~

7 *(b) (1) For purposes of this article, a "provider of blood clotting*  
8 *products for home use" shall be a provider of blood clotting*  
9 *products and ancillary infusion equipment for home use and*  
10 *consumer assistance for the management of bleeding disorders*  
11 *and may include, but is not limited to, any of the following:*

12 *(A) Hospital pharmacies.*

13 *(B) Health system pharmacies.*

14 *(C) Pharmacies affiliated with hemophilia treatment centers.*

15 *(D) Specialty home care pharmacies.*

16 *(E) Retail pharmacies.*

17 *(2) The providers described in this subdivision may also provide*  
18 *home nursing services for persons with bleeding disorders.*

19 125286.4. Each provider of blood clotting products for home  
20 use shall meet all of the following requirements:

21 (a) Have sufficient knowledge and understanding of bleeding  
22 disorders *to accurately follow the instructions of the prescribing*  
23 *physician and ensure high-quality service for the consumer* and  
24 the medical and psychosocial management thereof, including, but  
25 not limited to, home therapy.

26 (b) Have sufficient clinical experience providing services to  
27 persons with bleeding disorders and a sufficient nonclinical  
28 understanding of bleeding disorders that enables the provider to  
29 know when patients have an appropriate supply of clotting factor  
30 on hand and about proper refrigeration of clotting factors.

31 (c) Ensure that its customer service staff meets the requirements  
32 of subdivisions (a) and (b).

33 (d) Have knowledgeable pharmacy staffing on call 24 hours a  
34 day, to initiate emergency requests for clotting factors.

35 (e) Supply blood clotting products and home nursing services,  
36 as prescribed by the consumer's treating physician, and, pursuant  
37 to Section 4073 of the Business and Professions Code, not make  
38 any substitutions of blood clotting products or assay amounts.

39 (f) The prescribing physician shall indicate which specific blood  
40 clotting product is intended whenever a prescription is written.

1 (g) Supply all brands of blood clotting products approved by  
2 the federal Food and Drug Administration in multiple assay ranges  
3 (low, medium, and high, as applicable) and vial sizes, including  
4 products manufactured from human plasma and those manufactured  
5 with recombinant biotechnology techniques, provided manufacturer  
6 supply exists and payer authorization is approved.

7 (h) Supply all necessary ancillary infusion equipment and  
8 supplies with each prescription, as needed.

9 (i) Maintain adequate stocks of blood clotting products and  
10 ancillary infusion equipment and supplies.

11 (j) Store and ship, or otherwise deliver, all blood clotting  
12 products in conformity with all state and federally mandated  
13 standards, including, but not limited to, the standards set forth in  
14 the product's approved package insert (PI).

15 (k) When home nursing services are prescribed by the treating  
16 physician, provide these services either directly or through a  
17 qualified third party with experience in infusing bleeding disorders  
18 and coordinate pharmacy services with the third party when one  
19 is used to provide home nursing services.

20 (l) Upon receiving approved authorization for a nonemergency  
21 prescription, ship the prescribed blood clotting products and  
22 ancillary infusion equipment and supplies to the consumer within  
23 two business days or less for established and new consumers.

24 (m) Upon receiving approved authorization to dispense a  
25 prescription for an emergency situation, deliver prescribed blood  
26 products, ancillary infusion equipment and supplies, medications,  
27 and home nursing services to the consumer within 12 hours for  
28 patients living within 100 miles of a major metropolitan airport,  
29 and within one day for patients living more than 100 miles from  
30 a major metropolitan airport.

31 (n) Maintain 24-hour ~~on-call~~ *on call* service seven days a week  
32 for every day of the year, adequately screen phone calls for  
33 emergencies, and respond to all phone calls within one hour or  
34 less.

35 (o) Provide consumers who have ordered their products with a  
36 designated contact phone number for reporting problems with a  
37 delivery and respond to these calls immediately.

38 (p) Provide patients with notification of recalls and withdrawals  
39 of blood clotting products and ancillary infusion equipment within

1 24 hours and participate in the National Patient Notification System  
2 for blood clotting product recalls.

3 (q) Provide language translation services, both over the phone  
4 and in person, as needed by the consumer.

5 (r) Have a detailed plan for meeting the requirements of this  
6 article in the event of a natural or manmade disaster or other  
7 disruption of normal business operations.

8 (s) Provide for proper collection, removal, and disposal of  
9 hazardous waste pursuant to state and federal law, including, but  
10 not limited to, sharps containers for the removal and disposal of  
11 medical waste.

12 (t) Inform a consumer of his or her copay, deductible, and  
13 coinsurance payment responsibilities initially and when changed  
14 by the consumer's insurance, health plan, or other third-party payer.

15 (u) Provide consumers with a copy of all billing invoices.

16 (v) Provide appropriate and necessary recordkeeping and  
17 documentation as required by state and federal law and retain  
18 copies of the patient's prescriptions.

19 (w) Comply with the privacy and confidentiality requirements  
20 of the Health Insurance Portability and Accountability Act of 1996  
21 (HIPAA).

22 125286.5. ~~The~~(a) *Except as provided in subdivision (b), the*  
23 *California State Board of Pharmacy shall administer and enforce*  
24 *this article.*

25 (b) *The California State Board of Pharmacy shall not administer*  
26 *and enforce subdivision (f) of Section 125286.4.*